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Women's experiences of tests and procedures carried out at a preterm birth surveillance clinic --Manuscript Draft--

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Abstract:	This study sought to explore the experiences and views of pregnant women at high-risk of preterm birth who were undergoing tests requiring a speculum examination and procedures at a preterm birth surveillance clinic. There was a total of 102 participants who completed the questionnaire. Overall 97% (n=99) of women found the speculum examination acceptable and 88% (n=90) stated they would be happy to have the examination again if required. This was comparable to 95% (n=97) of women who stated they found the transvaginal ultrasound examination acceptable. Our findings suggest that women at risk of preterm birth find speculum examinations and transvaginal ultrasound scans for cervical length measurement acceptable.
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Women's experiences of tests and procedures carried out at a preterm birth surveillance clinic

Introduction

Preterm birth remains a major cause of neonatal morbidity and mortality, and in the United Kingdom (UK), 7.8% of babies born were born before 37 weeks gestation in the year 2010 (WHO, 2012). Some UK hospitals offer a specialist preterm birth service for women deemed to be at risk of a preterm birth or late miscarriage including those with a history of preterm birth, late miscarriage or cervical surgery. However practice in specialist preterm birth clinics varies in both surveillance methods and clinical management (Sharp & Alfirevic, 2014).

Surveillance methods are used to identify those women who may benefit from intervention, such as cerclage or progesterone treatment and closer monitoring (Min *et al.*, 2016). Methods include transvaginal ultrasound measurement of cervical length, and collection of vaginal fluid for evaluation using predictive biomarker tests such as Fetal Fibronectin, PartoSure™ or Actim® Partus.

Most biomarker tests require the use of a speculum, however one test, PartoSure™, does not and the reduced need for a speculum examination with a speculum may be more acceptable to some women. While there is more evidence to support the utility of quantitative Fetal Fibronectin (qfFn) in predicting preterm birth compared to Partosure™, Fetal Fibronectin does require the use of a speculum (Abbott *et al.*, 2013; Abbott *et al.*, 2015; Kurtzman *et al.*, 2009).

Although previous studies exploring transvaginal ultrasound scans in pregnancy have found them to be acceptable to women (Atalabi *et al.*, 2012; Bello & Odeku, 2015; Clement *et al.*, 2003), we found no studies focusing on women's experiences of speculum examinations in a pregnancy at high-risk of preterm delivery.

This study sought to explore the experiences and views of pregnant women at high-risk of preterm birth who were undergoing tests requiring a speculum examination and procedures at a preterm birth surveillance clinic.

Methods

Participants were a sub-set of women enrolled in the ***** study (REC Ref.*****). Women were enrolled through convenience sampling as they attended an appointment at an antenatal preterm surveillance clinic at a large UK inner-city teaching hospital between February and August 2011. All women presenting to the clinic were provided with the study questionnaire and were asked to return their completed paperwork anonymously after their appointment to the clinic receptionist. This ensured that women did not feel pressured by the clinical research staff working in the clinic.

Data collected included demographic information, parity and gestational age. Eight questions were asked about their experiences of the speculum examination and transvaginal ultrasound scan for cervical length measurement. These eight questions could be answered “yes”, “no” or “I don’t know”. The data were then collected and analysed on an Excel spreadsheet.

Results

There was a total of 102 participants who completed the questionnaire. Overall 97% (n=99) of women found the speculum examination acceptable and 88% (n=90) stated they would be happy to have the examination again if required. This was comparable to 95% (n=97) of women who stated they found the transvaginal ultrasound examination acceptable.

Participant characteristics

The age of the participants at time of completing the questionnaire ranged from 17 years to 44 years, with a mean and median age of 32 years.

The demographics of the participants can be seen in Table 1.

Table 1 Demographics of participants

	Number of participants n=	Percentage of participants %
Age Range		
> 20	2	2
20-24	7	7
25-29	14	14
30-34	45	44
35-39	25	26
40-44	4	4
No response	5	5
Ethnicity		
White British	29	28
White Other	16	16
Black African	27	26
Black Caribbean	8	8
Asian	6	6
Mixed race	3	3
Other	12	12
No response	1	1
Parity		
Nulliparous	53	52

Multiparous

49

48

The gestational age (GA) of the participants at the time of completing the questionnaire ranged from 18 to 34 weeks, with a mean and median GA of 22 weeks. 5 participants did not disclose their gestation.

Experience of having speculum examinations and procedures

Results for the remainder of the survey are presented in Table 2 and Figure 1.

Table 2 Patient responses to the questionnaire

	Yes		No		I don't know		No response	
	n	%	n	%	n	%	n	%
1. Did you find the speculum examination acceptable?	99	97	1	1	2	2	0	0
2.If "no", would you accept the test if it did not involve a speculum?	1	1	-	-	-	-	-	-
3. Did you understand why the test was done?	100	98	1	1	0	0	1	1

**4. Did you understand
what the test result
meant?**

89 86 0 0 5 5 8 8

**5. Would you be happy
to have the test again in
this pregnancy?**

90 88 4 4 5 5 3 3

**6. Would you be
prepared to take the
swab yourself without
the speculum?**

48 47 35 34 15 15 4 4

**7. Do you find the
cervical length scan
acceptable?**

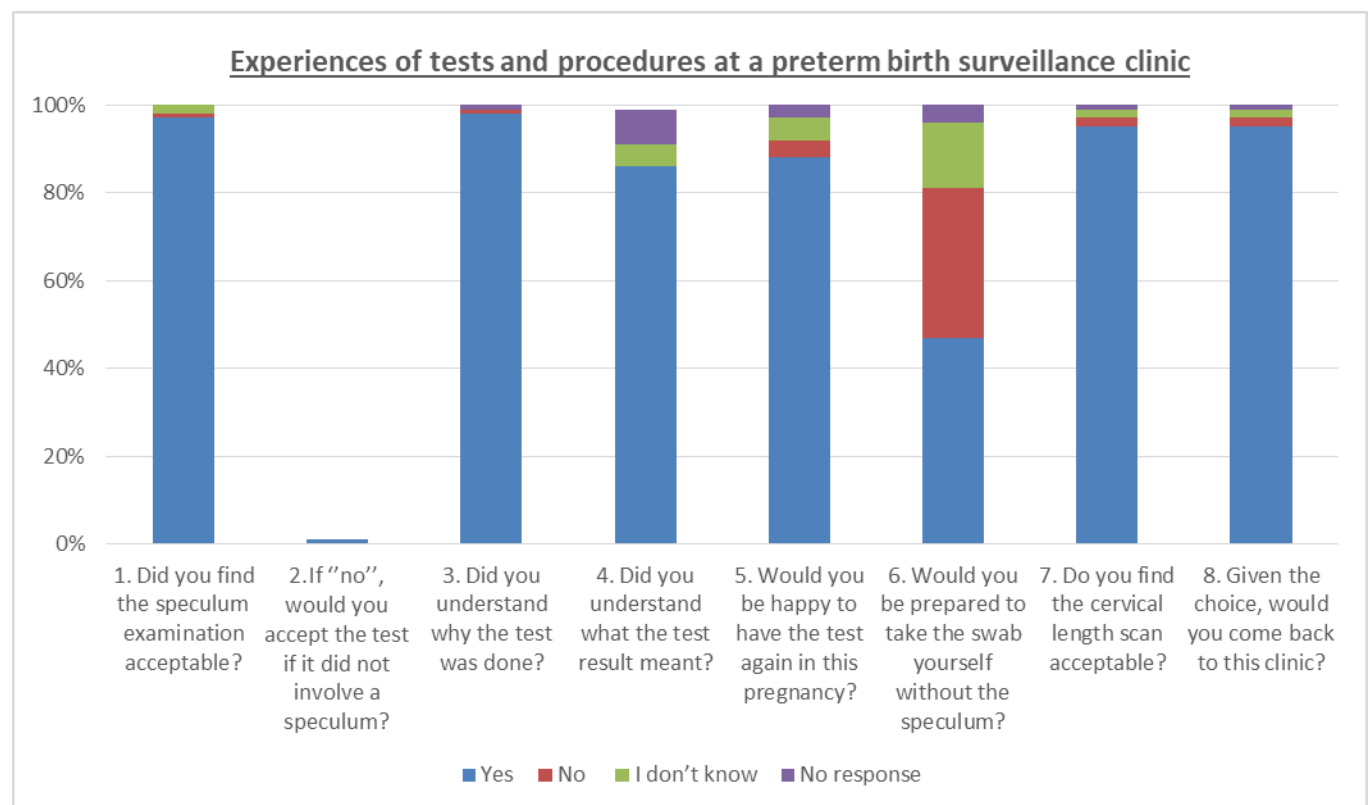
97 95 2 2 2 2 1 1

**8. Given the choice,
would you come back
to this clinic?**

97 95 2 2 2 2 1 1

Total n=102

Figure 1 Stacked column showing the participants' experiences of tests and procedures at the preterm birth surveillance clinic



Discussion

This is the first study exploring women's experience of speculum examination for preterm surveillance. Studies exploring women's experiences of a vaginal speculum examination suggest that they are associated with anxiety, embarrassment and discomfort (Hoyo *et al.*, 2005; Yanikkerem *et al.*, 2009). Anxiety in pregnancy is closely related to the woman's perception of her pregnancy being high-risk (Bayrampour *et al.*, 2012). Women attending preterm birth surveillance clinics are aware

that they are at high-risk, and therefore likely to be anxious and apprehensive even before any procedures or tests are carried out.

The majority of participants (99/102, 97%) found the speculum examination acceptable, with only one participant (1%) finding the speculum unacceptable. This one participant responded that they would have accepted the Fetal Fibronectin test if it had not involve a speculum. These results demonstrate that the vast majority of this pregnant cohort found the speculum examination acceptable.

This study found that 88% of participants who responded would be happy to have the test again in their current pregnancy, while 4% would not be happy to. These results are encouraging, as they suggest that this would not prevent the majority of women adhering to premature birth surveillance due to lack of acceptability with speculum use. Previous studies suggest that discomfort associated with speculum examinations may have led to some women not attending appointments for cervical cancer screening (Hoyo *et al.*, 2005).

Of participants who responded, 47% of women would be prepared to take the swab themselves without a speculum, while 34% of women would not be prepared to. As previous studies have found women's experiences of speculums as anxiety provoking, embarrassing and uncomfortable this was surprising. For example, a pilot study on speculum 'self-insertion' found that the majority of women were satisfied and would choose to self-insert a speculum again as it made the process less threatening (Wright *et al.*, 2005). These differences may be explained by the fact the women in this study were pregnant and in a 'high-risk' cohort. They may have fears of harming the pregnancy or their baby. As their gestation increases, women may also find it physically difficult to take their own vaginal swabs.

95% of women who responded found the transvaginal scan to measure their cervical length acceptable, while 2% of women did not. These results are similar to those in previous studies which

found that transvaginal ultrasound scans are acceptable to pregnant women (Atalabi *et al.*, 2012; Bello & Odeku, 2015; Clement *et al.*, 2003).

Limitations of this study include that no formal power calculation or advanced statistical analysis was performed on the data. Also as this was a convenience sample, there may be a possibility of selection bias. The women in this study were from an ethnically diverse background with a range of maternal ages and gestational ages. Caution must therefore be taken when applying these results to a different demographic of pregnant women.

Conclusions

Our findings suggest that women at risk of preterm birth find speculum examinations and transvaginal ultrasound scans for cervical length measurement acceptable. Any intimate examination should be approached with care, ensuring the patient is treated with dignity and respect and consent. While it is acknowledged that intimate medical examinations and procedures are not pleasant experiences, this study illustrates that the majority of pregnant women in a high-risk pregnancy are not opposed to them being performed.

More research is needed, however, to confirm this in a larger cohort using a formal power calculation and advanced statistical analysis. Further research could also focus on women's experience of speculum use in low-risk pregnancies (for example, for other swab tests), and if pregnant women would consider self-insertion of speculums.

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